

RULEMAKING NOTICE FORM

Notice Number 2015-136

Rule Number He-C 401 (various)

1. Agency Name & Address:

**NH Dept. of Health & Human Services
Therapeutic Cannabis Program
129 Pleasant St.
Concord, NH 03301**

2. RSA Authority:

RSA 126-X:6, I

3. Federal Authority:

4. Type of Action:

Adoption X

Amendment X*

Repeal _____

Readoption _____

Readoption w/amendment _____

5. Short Title: **Therapeutic Cannabis Program – Registry Rules**

6. (a) Summary of what the rule says and of any proposed amendments:

He-C 401 describes the requirements for the Therapeutic Cannabis Program Registry, including: (1) Application process for qualifying patients and designated caregivers to obtain a registry identification card (including processing, approval, denial, revocation, expiration, renewal, notifications, and fees); (2) Additional requirements for minor patients; (3) Healthcare provider requirements; (4) Requirements for the healthcare provider's written certification of a patient's qualifying condition; and (5) Petition process for conditions not listed as a qualifying medical condition.

***He-C 401 was adopted in July 2014, but is not scheduled to become effective until November 2015. Consequently, although some of the proposed rules are characterized as "amendments," there is no existing rule, so the "amendments" are technically "adoptions." This proposal is not intended to become effective until the rest of He-C 401 becomes effective, and so, when effective, this proposal will immediately change the original rule.**

The proposed rule makes the following changes to He-C 401, which although adopted in July 2014 is not scheduled to be effective until November 2015:

- **Implements HB 476 (Chapter 195 of the Laws of 2015), which adds epilepsy, lupus, and Parkinson's disease to the definition of "qualifying medical condition" and clarifies the description of Alzheimer's disease.**
- **Implements portions of SB 22 (Chapter 143 of the Laws of 2015), which removes the requirement for an annual submission of a photograph by qualifying patients and designated caregivers, and instead requires such photographs to be submitted every five years.**
- **Implements portions of SB 22 (Chapter 143 of the Laws of 2015), which removes the requirement for an annual submission of criminal history records check results by designated caregivers, and instead requires that an attestation of no felony conviction be submitted annually.**
- **Implements portions of SB 22 (Chapter 143 of the Laws of 2015), which (1) removes the Alternative Treatment Center registration number from the qualifying patient's registry identification card and (2) removes the qualifying patient's registry identification number from his or her designated caregiver's registry identification card.**

- Establishes a pre-registration process for qualifying patients and designated caregivers which will allow them to pre-register for a registry identification card but not receive the card until such time as the Alternative Treatment Center designated by the qualifying patient has been issued a registration certificate to dispense cannabis.
- Prohibits the production of a cannabis concentrate by a qualifying patient or designated caregiver using any extraction method other than that which is water or food based, violation of which shall be grounds for revocation of a registry identification card.
- Establishes that the department's process for accepting petitions for approving medical conditions not listed in RSA 126-X:1, IX(a) as a qualifying medical condition will begin in January 2017.

6. (b) Brief description of the groups affected:

This rule affects: (1) eligible qualifying patients who have been certified by their medical provider to have a qualifying medical condition and associated symptoms; (2) designated caregivers who are authorized to assist qualifying patients with the therapeutic use of cannabis; and (3) medical providers who certify qualifying patients' qualifying conditions.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	RSA Implemented
He-C 401.02 (c) & (k)	RSA 126-X:1
He-C 401.09 (b)	RSA 126-X:1, IX(b)
He-C 401.11 (b)	RSA 126-X:4, I-IV
He-C 401.12 (b)(12)	RSA 126-X:6, I(c)
He-C 401.13 (g) & (h)[deleted]	RSA 126-X:4, IX
He-C 401.18	RSA 126-X:6, I(c)
He-C 401.19	RSA 126-X:6, I(c)

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name:	Michael Holt	Title:	Rules Coordinator
Address:	Dept. of Health and Human Services Administrative Rules Unit 129 Pleasant St. Concord, NH 03301	Phone #:	271-9234
		Fax#:	271-5590
		E-mail:	michael.holt@dhhs.state.nh.us

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

The proposed rules may be viewed and downloaded at:

[**http://www.dhhs.nh.gov/oos/aru/comment.htm**](http://www.dhhs.nh.gov/oos/aru/comment.htm)

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **September 11, 2015**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Thursday, September 3, 2015 at 1:00 PM**

Place: [**DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH**](#)

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # 15:147, dated 08/11/15

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

He-C 401 is an adopted rule with an effective date of November 2, 2015. When compared to the adopted rule, the proposed rules may increase registry identification card and certificate fund expenditures (state funds) by an indeterminable amount.

2. Cite the Federal mandate. Identify the impact of state funds:

No federal mandate, no impact on state funds.

3. Cost and benefits of the proposed rule(s):

A. To State general or State special funds:

The proposed rules establish a new pre-registration process for registry identification card applicants and require the Department of Health and Human Services to notify each applicant in writing as to whether their application is approved or disapproved, resulting in an indeterminable cost to the registry identification card and certificate fund. The fund is supported by registration identification cards and alternative treatment center (ATC) fees and used to pay for the Therapeutic Use of Cannabis Program pursuant to RSA 126-X:1, et seq. There will be no impact on State general funds

B. To State citizens and political subdivisions:

Individuals participating in the therapeutic cannabis program will benefit from the proposed rules as they will no longer need to annually pay for and submit a photograph each year or have to pay for a replacement registry identification card when they change their designated ATC. Designated caregivers will no longer be required to pay for and submit an annual criminal history records check result. There will be no impact on political subdivisions.

C. To Independently owned businesses:

To the extent more individuals qualify for registry identification cards and purchase more therapeutic cannabis, ATCs could benefit from increased sales.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution.

CHAPTER He-C 400 THERAPEUTIC CANNABIS PROGRAM

PART He-C 401 THERAPEUTIC CANNABIS PROGRAM – REGISTRY RULES

Amend He-C 401.02, effective 11/2/15 (Document # 10646), by inserting new paragraph (c) and renumbering subsequent paragraphs, and amending paragraph (j), renumbered as paragraph (k), cited and to read as follows:

He-C 401.02 Definitions.

(c) “Cannabis concentrate” means any form of cannabinoid extracted from usable cannabis plant material using an extraction method, such as water, food, carbon dioxide, alcohol, or other solvent as allowed by He-C 402.16(j)(1)c.

~~(j)~~(k) “Qualifying medical condition” means “qualifying medical condition” as defined in RSA 126-X:1, IX(a), namely, “the presence of:

(1) Cancer, glaucoma, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, hepatitis C currently receiving antiviral treatment, amyotrophic lateral sclerosis, muscular dystrophy, Crohn’s disease, ~~agitation of Alzheimer’s disease~~, multiple sclerosis, chronic pancreatitis, spinal cord injury or disease, traumatic brain injury, epilepsy, lupus, Parkinson’s disease, Alzheimer’s disease, or one or more injuries that significantly interferes with daily activities as documented by the patient’s provider; and

(2) A severely debilitating or terminal medical condition or its treatment that has produced at least one of the following: elevated intraocular pressure, cachexia, chemotherapy-induced anorexia, wasting syndrome, ~~agitation of Alzheimer’s disease~~, severe pain that has not responded to previously prescribed medication or surgical measures or for which other treatment options produced serious side effects, constant or severe nausea, moderate to severe vomiting, seizures, or severe, persistent muscle spasms.”

Amend He-C 401.09(b), effective 11/2/15 (Document #10656), cited and to read as follows:

He-C 401.09 Approval of a Severely Debilitating or Terminal Medical Condition Not Listed as a Qualifying Medical Condition.

(b) The department shall accept petitions in the months of January and July of each year, beginning in January 2017.

Amend He-C 401.11(b), effective 11/2/15 (Document #10646), by inserting new subparagraphs (1)-(2) so that He-C 401.11(b) is cited and reads as follows:

He-C 401.11 Registry Identification Card Expirations and Procedures for Renewals.

(b) Each qualifying patient and designated caregiver shall complete and submit to the department application materials pursuant to He-C 401.04 or He-C 401.05 at least 30 days prior to the expiration of his or her current registry identification card-, except that:

(1) For qualifying patients and designated caregivers, the photograph required in He-C 401.04(b)(3) and He-C 401.05(b)(2), respectively, shall only be required to be submitted once every 5 years, provided there is no lapse in registration; and

(2) For designated caregivers, the criminal history records check results required by He-C 401.05(c) shall not be required, but the designated caregiver shall complete, sign under penalties set forth in RSA 641:3 for unsworn falsification, date, and submit an “Attestation of No Felony Conviction” form (October 2015), provided there has been no lapse in registration.

Amend He-C 401.12(b), effective 11/2/15 (Document #10646), by inserting new paragraph (b)(12) so that He-C 401.12(b) intro and paragraph (b)(12) are cited and read as follows:

He-C 401.12 Denial of an Application, Enforcement Actions, and Administrative Appeals.

(b) The department shall revoke a qualifying patient or designated caregiver’s registry identification card for any of the following:

(12) A qualifying patient or designated caregiver produces cannabis concentrate using an extraction method that is prohibited by He-C 401.18.

Amend He-C 401.13, effective 11/2/15 (Document #10646), by amending paragraph (g), and by deleting paragraph (h) and renumbering subsequent paragraphs, so that He-C 401.13(g) is cited and reads as follows:

He-C 401.13 Requirements for Notifications.

(g) A new registry identification card, including a new identification number, shall be issued within 20 days for any change to a qualifying patient’s or designated caregiver’s name, or address, ~~or alternative treatment center.~~

~~—— (h) A new registry identification card, but not a new identification number, shall be issued to a designated caregiver for any change to the identification number of a designated caregiver’s qualifying patient or if a qualifying patient has newly designated the caregiver.~~

Adopt He-C 401.18 and 401.19, to read as follows:

He-C 401.18 Production of Cannabis-Infused Products. A qualifying patient or designated caregiver may produce cannabis concentrate only through either a food or water based extraction method. All other extraction methods shall be prohibited.

He-C 401.19 Pre-registration.

(a) To ensure, to the greatest extent possible, the prompt and orderly issuance of registry identification cards at the outset of the therapeutic cannabis program, the department shall institute a pre-registration period beginning November 2, 2015. During the pre-registration period, potentially qualifying patients and designated caregivers may submit a completed application to pre-register for a registry identification card.

(b) Applications submitted during the pre-registration period shall conform to the requirements of He-C 401.04 and He-C 401.05, including the requirement to designate an alternative treatment center.

(c) During the pre-registration period, the department shall receive and process applications in accordance with He-C 401.10(a)-(e), and shall inform the applicant in writing whether or not he or she is approved for a registry identification card.

(d) Registry identification cards shall not be issued to qualifying patients and designated caregivers who submitted applications during the pre-registration period until the alternative treatment center designated by the qualifying patient applicant has been issued a registration certificate allowing it to dispense cannabis.

(e) Once an alternative treatment center has been issued a registration certificate allowing it to dispense cannabis, the department shall issue registry identification cards in accordance with He-C 401.10(f)-(g) to those qualifying patients who have designated that alternative treatment center in their application, as well as to their designated caregivers.

(f) Nothing in this section shall prevent a qualifying patient applicant from changing his or her alternative treatment center in accordance with He-C 401.13(a).

APPENDIX

RULE	STATUTE
He-C 401.02 (c) & (k)	RSA 126-X:1
He-C 401.09 (b)	RSA 126-X:1, IX(b)
He-C 401.11 (b)	RSA 126-X:4, I-IV
He-C 401.12 (b)(12)	RSA 126-X:6, I(c)
He-C 401.13 (g) & (h)[deleted]	RSA 126-X:4, IX
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